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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,257	02/15/2002	Yoram Reiter	02/23338	9820

7590

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/075,257		REITER, YORAM	
	Examiner		Art Unit	
	F. Pierre VanderVegt		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/534,966.

Claims 1-14 are currently pending.

Election/Restrictions

1. **Claims 1-4 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 22, 2004.

Claims 5-14 are the subject of examination in the present Office Action.

2. In view of Applicant's arguments filed November 29, 2004, the following ground of rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 5-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al (Proc. Nat. Acad. Sci. (USA) [1993] 90:10330-10334; U on form PTO-892) in view of Matsumura et al (J. Biol. Chem. [1992] 267(33): 23589-23595; V on form PTO-892).

It was previously stated: "Altman teaches a method for the production of soluble functional MHC class II complexes in *E. coli* (see entire document). Altman teaches the purification of MHC class II from inclusion bodies and the in vitro refolding of the MHC molecules. Altman teaches the association of the MHC molecules with antigenic peptides. Altman teaches that no other proteins are required for the efficient folding of the MHC molecules and that carbohydrate modification is not necessary for T cell recognition. Altman teaches that production in *E. coli* provides large quantities of MHC molecules needed for conformational and functional studies (page 10334 in particular). Altman teaches that production of empty MHC class I molecules is possible, but is inhibited by the instability of the complex at physiological temperatures (page 10334 in particular).

Altman does not teach the production of MHC class I molecules.

Matsumura teaches the production of soluble empty MHC class I molecules in *Drosophila melanogaster* cells and the binding of peptides to the complexes (see entire document).

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It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to use the method of Altman to produce the MHC class I molecules of Matsumura in *E. coli*. One would have been motivated to combine the teachings with a reasonable expectation of success by the teaching of Altman that MHC molecules do not need accessory molecules for folding and that they do not need glycosylation to be functional. One would have been further motivated by the teaching of Matsumura that empty MHC class I molecules are stable at lower temperature and can be loaded with antigenic peptides. It is well known in the art that *E. coli* can be easily cultivated at temperatures at least as low as 4 degrees C. Accordingly, the artisan would have expected to be able to produce large quantities of functional MHC class I molecules at a low cost through use of the combined methods.”

Applicant's arguments filed November 29, 2004 have been fully considered but they are not persuasive.

Applicant asserts that the Altman reference is not applicable because the MHC class I constructs taught by Altman are unstable at physiological temperatures. Applicant argues therefore that the MHC class I constructs of Altman are not functional. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., functional at physiological temperatures) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Altman teaches the association of the soluble MHC class I constructs with an antigenic peptide. This is an art-recognized function of MHC class I molecules and therefore fully satisfies the metes and bounds of the claims as presented. Accordingly, the ground of rejection is maintained.

Conclusion

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
February 16, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
2/17/05


F. PIERRE VANDERVEGT, PH.D.
PATENT EXAMINER